

Medical Policy

Policy: 200237

Initial Effective Date: 11/08/2002

SUBJECT: Chelation Therapy

Annual Review Date: 10/10/2023

Last Revised Date: 11/16/2023

Some or all procedure codes listed in this Corporate Medical Policy may be considered experimental/investigational.

Definition: Chelation therapy involves the use of chelating agents to bind heavy metal ions to form water-soluble complexes (excreted in the urine or feces), reportedly reducing excessive accumulation of essential heavy metals (e.g., iron, copper) and non-essential heavy metals (e.g., lead, aluminum) from the body. Chelating agents may be administered by intravenous, intramuscular, subcutaneous or oral routes.

Edetate disodium was voluntarily withdrawn from the United States market in 2008 after serious adverse events were reported.

Medical Necessity: The Company considers chelating agents approved by the U.S. Food and Drug Administration (**HCPCS Codes J0470, J0600, and J0895**) **medically necessary** and eligible for reimbursement providing that *at least one* of the following clinical conditions is present:

- Arsenic and its compounds; or
- Beryllium and its compounds; or
- Chromium and its compounds; or
- Copper and its compounds; or
- Disorder of copper metabolism, unspecified; or
- Disorder of iron metabolism, unspecified; or
- End stage renal disease; or
- Hemochromatosis due to repeated red blood cell transfusions; or
- Hemochromatosis, unspecified; or
- Hereditary hemochromatosis; or
- Hypercalcemia; or
- Manganese and its compounds; or
- Mercury and its compounds; or
- Mercury and its compounds; or
- Other disorders of copper metabolism; or
- Other disorders of iron metabolism; or
- Other hemochromatosis; or
- Other metals; or
- Poisoning by antirheumatics; or

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- Poisoning by heavy metal anti-infectives; or
- Poisoning by iron and its compounds; or
- Poisoning by other specified systemic anti-infectives and antiparasitic; or
- Poisoning by propionic acid derivatives; or
- Sickle-cell disease; or
- Thalassemia; or
- Thallium; or
- Tin and its compounds; or
- Toxic effect of lead and its compounds (including fumes); or
- Unspecified metal; or Wilson's disease; or Zinc and its compounds.

The Company considers chelation therapy utilizing edetate disodium (**HCPCS Code J3520**) **not medically necessary** and **not** eligible for reimbursement.

The Company considers home infusion chelation therapy (**HCPCS Code S9355**) a **non-covered benefit** and **not** eligible for reimbursement.

The Company considers chemical endarterectomy (**HCPCS Code M0300**) **investigational** and **not** eligible for reimbursement.

The Company considers chelation therapy **not medically necessary** and **not** eligible for reimbursement for **all** other clinical conditions including, but not limited to, the following:

- Alzheimer's disease; or
- Arteriosclerotic heart disease; or
- Arthritis; or
- Autism; or
- Cancer
- Chronic fatigue syndrome due to dental amalgam therapy (mercury)
- Coronary artery disease; or
- Diabetes; or
- Huntington
- Hypercholesterolemia; or
- Hypoglycemia; or
- Multiple sclerosis; or
- Parkinson's disease; or
- Peripheral vascular disease; or
- Porphyria; or
- Rheumatoid arthritis; or
- Scleroderma.

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Laboratory testing for heavy metal toxicity: The Company considers laboratory testing for heavy metal poisoning **medically necessary** and eligible for reimbursement in the presence of symptoms consistent with heavy metal toxicity and/or in the presence of exposure to heavy metals. Screening for heavy metal poisoning in the presence of poorly defined symptoms (e.g., malaise, fatigue) or no history of exposure to heavy metals is considered **not medically necessary** and **not** eligible for reimbursement.

NOTE: If coverage for chelation therapy is denied, all related services (e.g., Evaluation and Management services, laboratory studies, infusion services) will also be denied with the same denial code as the chelation therapy.

Note: The Company will not cover treatment of any heavy metal intoxication as the result of an occupational exposure or due to a workers compensation claim.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the service, or procedure, supply, product, or accommodation performed or furnished regardless of how the service, or procedure, supply, product, or accommodation was coded by the Provider.

Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.

Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.

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Sources of Information:

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Applicable Code(s):	
CPT:	
HCPCS:	J0470, J0600, J0895, M0300, S9355
ICD10 Procedure Codes:	